May 10, 2010

Alfred V. Almanza
Administrator
Food Safety and Inspection Service
US Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250-3700

Docket Clerk, FSIS
Room 2-2127
5601 Sunnyside Avenue
Beltsville, MD 20705

Re: Draft Guidance on HACCP System Validation

Dear Administrator Almanza:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Section 612 of the Regulatory Flexibility Act (RFA) requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1] Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

I am writing because my office has received several communications from small businesses and their associations that are concerned with the March 19, 2010, letter and attached agency guidance sent by you to various meat and poultry entities. Your letter was in response to their letter dated September 22, 2009, outlining their understanding of Hazard Analysis and Critical Control Point (HACCP) systems validation. Also, the SBA's Office of the National Ombudsman referred various small business inquiries to Advocacy relative to this matter. While my office supports the public policy behind ensuring food safety, small businesses—which comprise a large number of the entities that are covered by the Food Safety and Inspection Service's (FSIS) guidance—are concerned that the agency clarification of the requirements of systems validation will result in a significant economic impact upon their industry.

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. § 612(a).

Background

On July 25, 1996, FSIS published the Pathogen Reduction: HACCP Systems Final Rule (61 FR 38806), Docket No. 93-016F. This document presented the validation requirements for meat and poultry establishments in 9 CFR 417.4. The regulation states each establishment is required to validate the effectiveness of its HACCP plans in controlling those food safety hazards identified during the hazard analysis. The regulation also states that establishments are to conduct these validation activities during the establishment's initial experience with a new HACCP plan and encompasses additional activities that make up the entire HACCP system. In addition to the regulatory language, the final rule also states what constitutes validation.

On September 22, 2009, various meat and poultry organizations wrote FSIS with their understanding of HACCP validation and with suggestions to incorporate in the agency's validation clarification documents under development and review. Administrator Almanza responded on March 19, 2010, and provided the agency's position on the issues raised by the organizations, signaling that the agency intends to issue a number of documents to clarify the requirements of HACCP validation as described in the 1996 final rule. FSIS included a compliance guidance document tailored for small and very small establishments to assist them in complying with the validation requirements. [2] FSIS noted that plants that do not incorporate these principles into their HACCP systems would raise questions whether the HACCP system has been adequately validated. FSIS made the compliance guidance document available for public comment.

Small Business Concerns

The businesses and industry groups that have contacted Advocacy suggest that food safety has always been of preeminent concern even before HACCP rules were promulgated and that implementation of the new system validation procedures will only add confusion and cost to a food safety system that is working under the current regulatory framework.

The concerned meat and poultry entities are primarily worried about FSIS' increased requirements for in-house microbiological testing of meat products to control pathogens instead of relying on pre-existing HACCP food safety systems. These businesses uniformly suggest that the requirements for microbiological testing will be extremely costly and a huge financial burden on small businesses in the meat and poultry industry as they operate on small revenue margins. The letters reviewed by Advocacy assert that the initial cost for system validation will be from $60,000 to $235,000 with annual costs ranging from $30,000 to $70,000. The businesses believe that FSIS should not mandate

[2] Advocacy commends the FSIS for complying with Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) by providing affected businesses with compliance guidance. Section 212 states: "For each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under section 604 of the Regulatory Flexibility Act, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as 'small entity compliance guides.'"

in-house microbiological testing and they question whether sufficient testing facilities exist in certain areas of the country to handle the increased testing required by the guidance. As a result of the information contained in the validation system guidance, small businesses question whether they will be able to produce the same number of products for the consumer, and they voice real concern as to whether they will be able to stay in business.

If FSIS' guidance document requires additional and/or increased microbiological testing as part of its review of the affected businesses' meat and poultry HAACP system validation, Advocacy would encourage the agency to consider proceeding through rulemaking rather than guidance. This would allow the affected businesses to provide FSIS with public comments on the agency's proposals adding to the rule's transparency. Also, pursuant to the RFA, the agency would either have to certify that this regulation would not have a significant impact on a substantial number of small entities along with a factual basis for the certification,[3] or perform an Initial Regulatory Flexibility Analysis (IRFA).[4] Advocacy suggests that by pursuing system validation through rulemaking FSIS would be in a position to analyze any benefits that would inure from increased system validation processes, any economic impacts that would result from the system validation procedures and whether any reasonable alternatives exist that would reduce the cost of the rule on small businesses.

Thank you for your attention to the above matter. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel, Linwood Rayford at (202) 401-6880, or www.linwood.rayford@sba.gov.

Sincerely yours,

/s/

Susan M. Walthall
Acting Chief Counsel Advocacy

/s/

Linwood L. Rayford, III
Assistant Chief Counsel for Food, Drug
And Health Affairs

cc: Esther H. Vassar, National Ombudsman, U.S. Small Business Administration
Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs

[3] See section 605 of the RFA.
[4] See section 603 of the RFA as to the analytical requirements of an IRFA.